

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

## PCT

To:

see form PCT/ISA/220

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**  
(PCT Rule 43bis.1)

Date of mailing  
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference  
see form PCT/ISA/220

**FOR FURTHER ACTION**  
See paragraph 2 below

International application No.  
PCT/GB2004/004462

International filing date (day/month/year)  
21.10.2004

Priority date (day/month/year)  
22.10.2003

International Patent Classification (IPC) or both national classification and IPC  
G01N33/49

Applicant  
UNIPATH LIMITED

**1. This opinion contains indications relating to the following items:**

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

**2. FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

**3. For further details, see notes to Form PCT/ISA/220.**

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**WRITTEN OPINION OF THE  
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**Box No. I Basis of the opinion**

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1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
  - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
  - a. type of material:
    - ☐ a sequence listing
    - ☐ table(s) related to the sequence listing
  - b. format of material:
    - ☐ in written format
    - ☐ in computer readable form
  - c. time of filing/furnishing:
    - ☐ contained in the international application as filed.
    - ☐ filed together with the international application in computer readable form.
    - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

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**Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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1. Statement

Novelty (N)	Yes: Claims	2-8,10-15,17-20
	No: Claims	1,9,16
Inventive step (IS)	Yes: Claims	
	No: Claims	1-20
Industrial applicability (IA)	Yes: Claims	1-20
	No: Claims	

2. Citations and explanations

**see separate sheet**

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**Box No. VII Certain defects in the international application**

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The following defects in the form or contents of the international application have been noted:

**see separate sheet**

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**Box No. VIII Certain observations on the international application**

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The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

**see separate sheet**

**Section V:**

1. Reference is made to the following documents:

D1: US-A-3 650 698

D2: US-A-5 110 727

2. Document D1 describes a method of detecting coagulation of a fluid comprising providing a magnetic field to cause particles to move within the fluid, illuminating the fluid and optically detecting the movement of the particles through a predetermined location in the fluid (in D1 implicitly (non-)movement of the particles is detected when the sample fluid becomes transparent).  
A similar disclosure can be found in document D2 (in D2 "oscillation" of the particles is detected which is considered to fall under the term "movement of the particles").  
Moreover it appears, that the illumination of the sample spots on the film strip of D1 is comparable to the step of "detecting the presence of the particles at a predetermined location in the fluid".

It is thus held that the subject-matter of claim 1 lacks novelty over both D1 and D2 (Article 33(2) PCT).

3. The apparatus' as disclosed in D1 and D2 are also suitable for performing the method of claim 1 i.e. fall within the wording of claim 9 (Article 33(2) PCT). The same holds for the "structure" as defined in claim 16 (see particularly D2, figure 16).
4. Independent claims 3, 4, 11 and 13 in principle describe similar subject-matter as the above claims by means of a different wording. At present it appears that such a definition adds nothing new and inventive, respectively, to the above independent claims of the same category.

At present it is also not apparent for which technical problem the features of the dependent claims would provide an inventive solution. The different types of particles, the use of electromagnetic equipment and the arrangement of the optical detection means are all measures which are known to the person skilled in the art.

5. Industrial applicability is acknowledged (Article 33(4) PCT).

**Section VII:**

1. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1 and D2 is not mentioned in the description, nor is this document identified therein.
2. The independent claims are not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (document D1/D2) being placed in a preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in a characterising part (Rule 6.3(b)(ii) PCT).
3. The features of the device claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

**Section VIII:**

1. The way of defining the invention in terms of seven independent claims 1, 3, 4, 9, 11, 13 and 16 makes it impossible, to determine the matter for which protection is sought, and places an undue burden on others seeking to establish the extent of the protection.

In order to overcome this objection, it would appear appropriate to file an amended set of claims defining the relevant subject-matter in terms of a single independent claim in each category followed by dependent claims covering features which are merely optional (Rule 6.4 PCT).